

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

QIAGEN HAMBURG GMBH and QIAGEN,
LLC,

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC.,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs QIAGEN Hamburg GmbH and QIAGEN, LLC, by and through their undersigned counsel, file this Complaint for Declaratory Judgment against Bio-Rad Laboratories, Inc., and allege as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of non-infringement arising under the patent laws of the United States, Title 35 of the United States Code. Plaintiffs QIAGEN Hamburg GmbH and QIAGEN, LLC (collectively “QIAGEN”) request this relief because Defendant Bio-Rad Laboratories, Inc. (“Bio-Rad”) has threatened QIAGEN¹ and claimed that QIAGEN infringes United States Patent Nos. RE41780 (the “’780 patent”) (Exhibit A), 10,782,226 (the “’226 patent”) (Exhibit B), 10,921,237 (the “’237 patent”) (Exhibit C), 11,073,468 (the “’468 patent”) (Exhibit

¹ The threat was to QIAGEN Hamburg GmbH; however, it concerned products sold by QIAGEN, LLC, therefore QIAGEN, LLC joins this lawsuit as a co-plaintiff.

D), 11,231,355 (the “’355 patent”) (Exhibit E) and 11,237,096 (the “’096 patent”) (Exhibit F) (collectively, the “Bio-Rad patents”).

2. QIAGEN provides sampling and assay products for a variety of molecular biology applications.

3. One of these products is QIAGEN’s QIAcuity® Digital Polymerase Chain Reaction (“PCR”) system. PCR is a biochemical method of amplifying a particular strand of target DNA and tagging it with a fluorescent marker. Amplification of the target DNA and its subsequent tagging then allows the detection and measurement of very small initial concentrations of DNA. PCR has medical and research applications. The QIAcuity system in particular delivers precise, comprehensive, and rapid results. Among other uses, it has recently found a use in 48 out of 50 states in testing municipal wastewater for signs of COVID-19. Testing municipal wastewater assists public health officials in tracking, tracing, and treating COVID-19 infections.

4. Bio-Rad is a company that also manufactures a variety of biochemical and biomedical research and diagnostic tools.

5. On May 27, 2021, Bio-Rad sent QIAGEN a letter accusing QIAGEN’s QIAcuity system of practicing “at least” the ’780, ’226, and ’237 patents. *See* May 27, 2021 Letter, Exhibit G at 1. The letter stated that Bio-Rad believed that “Qiagen’s QIAcuity® Digital PCR System utilizes Bio-Rad’s patented technology without authorization.” *Id.* at 3.

6. On February 10, 2022, Bio-Rad sent QIAGEN another letter escalating the dispute. In that letter, Bio-Rad reasserted the patents identified in the first letter, and further accused QIAGEN of practicing the newly issued ’468, ’355, and ’096 patents.

7. QIAGEN has denied that it infringes any claims of the Bio-Rad patents.

8. Since Bio-Rad sent its initial letter to QIAGEN, the parties have attempted to negotiate and settle the issues outside of court. However, it has become clear that the parties cannot resolve this issue without court assistance, and QIAGEN believes further discussions would be futile in their current form. Due to the imminent threat of a lawsuit being brought against it, QIAGEN files suit in Delaware, the state in which Bio-Rad is incorporated.

THE PARTIES

9. QIAGEN Hamburg GmbH is a Gesellschaft mit beschränkter Haftung (“GmbH”) (a company with limited liability) headquartered in Monheim am Rhein, North Rhine-Westphalia in the Federal Republic of Germany.

10. QIAGEN, LLC is a California limited liability company with an office at 1700 Seaport Blvd Ste 300, Redwood City, CA 94063.

11. On information and belief, Defendant Bio-Rad is a Delaware corporation with its principal place of business at 800 Alfred Nobel Dr., Hercules, California. Upon information and belief, Bio-Rad has consented to and agreed that the courts of Delaware have jurisdiction to resolve disputes between itself and other parties.

JURISDICTION AND VENUE

12. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201, and under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1332, 1338, 2201, and 2202 because this Court has exclusive jurisdiction over declaratory judgment claims arising under the patent laws of the United States pursuant to 28 U.S.C. §§ 1332, 1338, 2201, and 2202.

14. Bio-Rad is subject to general jurisdiction in Delaware because it is a Delaware Corporation. It is subject to specific personal jurisdiction in this judicial district based upon its purposeful, systematic, and continuous contacts with Delaware.

15. This Court can provide the declaratory relief brought in this Declaratory Judgment Complaint because an actual case and controversy exists between the parties within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201. An actual case and controversy exists at least because QIAGEN does not infringe and has not infringed any of the claims of the Bio-Rad patents, and Bio-Rad has accused QIAGEN of infringing the Bio-Rad patents. Bio-Rad's actions have created a real, live, immediate, and justiciable case or controversy between Bio-Rad and QIAGEN. Bio-Rad has taken the affirmative act to enforce its purported patent rights by explicitly alleging that QIAGEN is infringing its patents. QIAGEN alleges, upon information and belief, that Bio-Rad is attempting to assert or license the Bio-Rad patents against others as well.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400, including because venue in declaratory judgment actions for non-infringement of patents is determined under the general venue statute, 28 U.S.C. § 1391.

17. Under 28 U.S.C. § 1391(b)(1), venue is proper in any judicial district where a defendant resides. Because Bio-Rad is incorporated in this District, Bio-Rad resides in the District of Delaware and venue is proper under 28 U.S.C. § 1391.

THE ASSERTED PATENTS

18. On September 28, 2010, the United States Patent and Trademark Office (the "Patent Office") issued the '780 patent, entitled "Chemical Amplification Based on Fluid Partitioning in an Immiscible Liquid" to Brian L. Anderson, Bill W. Colston, and Christopher J. Elkin. A true and correct copy of the '780 patent is attached as Exhibit A. On information and belief, Bio-Rad purports to be the owner by assignment or the exclusive licensee of the '780 patent.

19. The '780 patent is a reissue of United States Patent No. 7,041,481, which issued on May 9, 2006 from U.S. Patent Application No. 10/389,130 filed on March 14, 2003.

20. On September 22, 2020, the Patent Office issued the '226 patent, entitled "Cell Capture System and Method of Use" to Kalyan Handique. A true and correct copy of the '226 patent is attached as Exhibit B. On information and belief, Bio-Rad purports to own by assignment the '226 patent.

21. The '226 patent issued from U.S. Patent Application No. 16/929,427 filed on July 15, 2020.

22. On February 16, 2021, the Patent Office issued the '237 patent, entitled "Cell Capture System and Method of Use" to Kalyan Handique. A true and correct copy of the '237 patent is attached as Exhibit C. On information and belief, Bio-Rad purports to own by assignment the '237 patent.

23. The '237 patent issued from U.S. Patent Application No. 17/005,611 filed on August 28, 2020.

24. On July 27, 2021, the Patent Office issued the '468 patent, entitled "Cell Capture System and Method of Use" to Kalyan Handique. A true and correct copy of the '468 patent is attached as Exhibit D. On information and belief, Bio-Rad purports to own by assignment the '468 patent.

25. The '468 patent issued from U.S. Patent Application No. 17/005,159 filed on August 27, 2020.

26. On January 25, 2022, the Patent Office issued the '355 patent, entitled "Cell Capture System and Method of Use" to Kalyan Handique. A true and correct copy of the '355

patent is attached as Exhibit E. On information and belief, Bio-Rad purports to own by assignment the '355 patent.

27. The '355 patent issued from U.S. Patent Application No. 17/241,897 filed on April 27, 2021.

28. On February 1, 2022, the Patent Office issued the '096 patent, entitled "Cell Capture System and Method of Use" to Kalyan Handique. A true and correct copy of the '096 patent is attached as Exhibit F. On information and belief, Bio-Rad purports to own by assignment the '096 patent.

29. The '096 patent issued from U.S. Patent Application No. 17/387,716 filed on July 28, 2021.

FIRST CLAIM FOR RELIEF

(Declaratory Judgment that QIAGEN Does Not Infringe the '780 Patent)

30. QIAGEN repeats and realleges each and every allegation contained in paragraphs 1 through 29 of this Complaint as if fully set forth herein.

31. In view of the facts and allegations set forth above, there is an actual, justiciable, substantial, and immediate controversy between QIAGEN and Bio-Rad regarding whether QIAGEN infringes any claim of the '780 patent.

32. Bio-Rad has alleged and continues to allege that products made, used, or sold by QIAGEN, or QIAGEN products that utilize certain methods of use, are covered by the claims of the '780 patent, and has threatened to commence litigation against QIAGEN regarding this matter.

33. QIAGEN contends that it has not infringed and does not infringe, induce infringement, or contribute to the infringement of any valid or enforceable claim of the '780 patent. QIAGEN has not made, used, sold, offered for sale, or imported any products that literally infringe, directly or indirectly, each and every claim of the '780 patent.

34. For example, and without limitation, QIAGEN's accused product does not practice the limitation "means for partitioning said sample into partitioned sections, wherein said means for partitioning said sample into partitioned sections comprises an injection orifice," of claim 1.

35. Therefore, a substantial controversy exists between QIAGEN and Bio-Rad, parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that QIAGEN has not infringed and does not infringe any valid or enforceable claim of the '780 patent.

36. An actual and justiciable controversy exists between QIAGEN and Bio-Rad as to whether QIAGEN's products infringe the '780 patent. QIAGEN accordingly requests a judicial determination of its rights, duties, and obligations regarding the '780 patent.

37. A judicial declaration is necessary and appropriate so that QIAGEN may ascertain its rights regarding the '780 patent.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment that QIAGEN Does Not Infringe the '226 Patent)

38. QIAGEN repeats and realleges each and every allegation contained in paragraphs 1 through 29 of this Complaint as if fully set forth herein.

39. In view of the facts and allegations set forth above, there is an actual, justiciable, substantial, and immediate controversy between QIAGEN and Bio-Rad regarding whether QIAGEN infringes any claim of the '226 patent.

40. Bio-Rad has alleged and continues to allege that products made, used, or sold by QIAGEN, or QIAGEN products that utilize certain methods of use, are covered by the claims of the '226 patent, and has threatened to commence litigation against QIAGEN regarding this matter.

41. QIAGEN contends that it has not infringed and does not infringe, induce infringement, or contribute to the infringement of any valid or enforceable claim of the '226 patent.

QIAGEN has not made, used, sold, offered for sale, or imported any products that literally infringe, directly or indirectly, each and every claim of the '226 patent.

42. For example, and without limitation, QIAGEN's accused product does not practice the limitation "an outlet channel positioned downstream of the set of chambers and fluidly coupled to the set of chambers, wherein fluid from the inlet channel reaches the outlet channel only by way of the set of chambers" of claim 1.

43. Therefore, a substantial controversy exists between QIAGEN and Bio-Rad, parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that QIAGEN has not infringed and does not infringe any valid or enforceable claim of the '226 patent.

44. An actual and justiciable controversy exists between QIAGEN and Bio-Rad as to whether QIAGEN's products infringe the '226 patent. QIAGEN accordingly requests a judicial determination of its rights, duties, and obligations regarding the '226 patent.

45. A judicial declaration is necessary and appropriate so that QIAGEN may ascertain its rights regarding the '226 patent.

THIRD CLAIM FOR RELIEF

(Declaratory Judgment that QIAGEN Does Not Infringe the '237 Patent)

46. QIAGEN repeats and realleges each and every allegation contained in paragraphs 1 through 29 of this Complaint as if fully set forth herein.

47. In view of the facts and allegations set forth above, there is an actual, justiciable, substantial, and immediate controversy between QIAGEN and Bio-Rad regarding whether QIAGEN infringes any claim of the '237 patent.

48. Bio-Rad has alleged and continues to allege that products made, used, or sold by QIAGEN, or QIAGEN products that utilize certain methods of use, are covered by the claims of the '237 patent, and has threatened to commence litigation against QIAGEN regarding this matter.

49. QIAGEN contends that it has not infringed and does not infringe, induce infringement, or contribute to the infringement of any valid or enforceable claim of the '237 patent. QIAGEN has not made, used, sold, offered for sale, or imported any products that literally infringe, directly or indirectly, each and every claim of the '237 patent.

50. For example, and without limitation, QIAGEN's accused product does not practice the limitation "an outlet channel positioned downstream of the set of chambers and fluidly coupled to the set of chambers, wherein fluid from the inlet channel reaches the outlet channel only by way of the set of chambers" of claim 1.

51. Therefore, a substantial controversy exists between QIAGEN and Bio-Rad, parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that QIAGEN has not infringed and does not infringe any valid or enforceable claim of the '237 patent.

52. An actual and justiciable controversy exists between QIAGEN and Bio-Rad as to whether QIAGEN's products infringe the '237 patent. QIAGEN accordingly requests a judicial determination of its rights, duties, and obligations regarding the '237 patent.

53. A judicial declaration is necessary and appropriate so that QIAGEN may ascertain its rights regarding the '237 patent.

FOURTH CLAIM FOR RELIEF

(Declaratory Judgment that QIAGEN Does Not Infringe the '468 Patent)

54. QIAGEN repeats and realleges each and every allegation contained in paragraphs 1 through 29 of this Complaint as if fully set forth herein.

55. In view of the facts and allegations set forth above, there is an actual, justiciable, substantial, and immediate controversy between QIAGEN and Bio-Rad regarding whether QIAGEN infringes any claim of the '468 patent.

56. Bio-Rad has alleged and continues to allege that products made, used, or sold by QIAGEN, or QIAGEN products that utilize certain methods of use, are covered by the claims of the '468 patent, and has threatened to commence litigation against QIAGEN regarding this matter.

57. QIAGEN contends that it has not infringed and does not infringe, induce infringement, or contribute to the infringement of any valid or enforceable claim of the '468 patent. QIAGEN has not made, used, sold, offered for sale, or imported any products that literally infringe, directly or indirectly, each and every claim of the '468 patent.

58. For example, and without limitation, QIAGEN's accused product does not practice the limitation "an outlet channel positioned downstream of the set of chambers and fluidly coupled to the set of chambers, wherein fluid from the inlet channel reaches the outlet channel only by way of the set of chambers" of claim 1.

59. Therefore, a substantial controversy exists between QIAGEN and Bio-Rad, parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that QIAGEN has not infringed and does not infringe any valid or enforceable claim of the '468 patent.

60. An actual and justiciable controversy exists between QIAGEN and Bio-Rad as to whether QIAGEN's products infringe the '468 patent. QIAGEN accordingly requests a judicial determination of its rights, duties, and obligations regarding the '468 patent.

61. A judicial declaration is necessary and appropriate so that QIAGEN may ascertain its rights regarding the '468 patent.

FIFTH CLAIM FOR RELIEF

(Declaratory Judgment that QIAGEN Does Not Infringe the '355 Patent)

62. QIAGEN repeats and realleges each and every allegation contained in paragraphs 1 through 29 of this Complaint as if fully set forth herein.

63. In view of the facts and allegations set forth above, there is an actual, justiciable, substantial, and immediate controversy between QIAGEN and Bio-Rad regarding whether QIAGEN infringes any claim of the '355 patent.

64. Bio-Rad has alleged and continues to allege that products made, used, or sold by QIAGEN, or QIAGEN products that utilize certain methods of use, are covered by the claims of the '355 patent, and has threatened to commence litigation against QIAGEN regarding this matter.

65. QIAGEN contends that it has not infringed and does not infringe, induce infringement, or contribute to the infringement of any valid or enforceable claim of the '355 patent. QIAGEN has not made, used, sold, offered for sale, or imported any products that literally infringe, directly or indirectly, each and every claim of the '355 patent.

66. For example, and without limitation, QIAGEN's accused product does not practice the limitation "wherein flow from the inlet channel is configured to reach the outlet channel only upon passing into the set of compartments" of claim 1.

67. Therefore, a substantial controversy exists between QIAGEN and Bio-Rad, parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that QIAGEN has not infringed and does not infringe any valid or enforceable claim of the '355 patent.

68. An actual and justiciable controversy exists between QIAGEN and Bio-Rad as to whether QIAGEN's products infringe the '355 patent. QIAGEN accordingly requests a judicial determination of its rights, duties, and obligations regarding the '355 patent.

69. A judicial declaration is necessary and appropriate so that QIAGEN may ascertain its rights regarding the '355 patent.

SIXTH CLAIM FOR RELIEF

(Declaratory Judgment that QIAGEN Does Not Infringe the '096 Patent)

70. QIAGEN repeats and realleges each and every allegation contained in paragraphs 1 through 29 of this Complaint as if fully set forth herein.

71. In view of the facts and allegations set forth above, there is an actual, justiciable, substantial, and immediate controversy between QIAGEN and Bio-Rad regarding whether QIAGEN infringes any claim of the '096 patent.

72. Bio-Rad has alleged and continues to allege that products made, used, or sold by QIAGEN, or QIAGEN products that utilize certain methods of use, are covered by the claims of the '096 patent, and has threatened to commence litigation against QIAGEN regarding this matter.

73. QIAGEN contends that it has not infringed and does not infringe, induce infringement, or contribute to the infringement of any valid or enforceable claim of the '096 patent. QIAGEN has not made, used, sold, offered for sale, or imported any products that literally infringe, directly or indirectly, each and every claim of the '096 patent.

74. For example, and without limitation, QIAGEN's accused product does not practice the limitation "an outlet channel positioned downstream of the set of chambers and fluidly coupled to the set of chambers, wherein fluid from the inlet channel reaches the outlet channel only by way of the set of chambers" of claim 1.

75. Therefore, a substantial controversy exists between QIAGEN and Bio-Rad, parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that QIAGEN has not infringed and does not infringe any valid or enforceable claim of the '096 patent.

76. An actual and justiciable controversy exists between QIAGEN and Bio-Rad as to whether QIAGEN's products infringe the '096 patent. QIAGEN accordingly requests a judicial determination of its rights, duties, and obligations regarding the '096 patent.

77. A judicial declaration is necessary and appropriate so that QIAGEN may ascertain its rights regarding the '096 patent.

JURY DEMAND

78. Pursuant to Federal Rule of Civil Procedure 38(b), QIAGEN demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

QIAGEN respectfully requests the following relief:

- a) That the Court enter a judgment declaring that QIAGEN has not infringed and does not infringe any valid or enforceable claim of U.S. Patent No. RE41780;
- b) That the Court enter a judgment declaring that QIAGEN has not infringed and does not infringe any valid or enforceable claim of U.S. Patent No. 10,782,226;
- c) That the Court enter a judgment declaring that QIAGEN has not infringed and does not infringe any valid or enforceable claim of U.S. Patent No. 10,921,237;
- d) That the Court enter a judgment declaring that QIAGEN has not infringed and does not infringe any valid or enforceable claim of U.S. Patent No. 11,073,468;
- e) That the Court enter a judgment declaring that QIAGEN has not infringed and does not infringe any valid or enforceable claim of U.S. Patent No. 11,231,355;
- f) That the Court enter a judgment declaring that QIAGEN has not infringed and does not infringe any valid or enforceable claim of U.S. Patent No. 11,237,096;
- g) That the Court declare that this case is exceptional under 35 U.S.C. § 285 and award QIAGEN its attorneys' fees, costs, and expenses incurred in this action;

- h) That the Court award QIAGEN any and all other relief to which QIAGEN may show itself to be entitled; and
- i) That the Court award QIAGEN any other relief as the Court may deem just, equitable, and proper.

Dated: April 6, 2022

Respectfully submitted,

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